

WEEK ENDING JUNE 7, 2013

# **OPP Weekly Activity Report**

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#### PESTICIDE RE-EVALUATION DIVISION

Conference Call Held with ETO Registrant to Discuss Information Request for Registration Review. On June 4, the Agency held a conference call with the ethylene oxide (ETO) technical registrant, Honeywell. The purpose of the conference call was to clarify the information that the Agency requested for registration review and to discuss Honeywell's future plans for their ETO products. Representatives from AD and PRD participated in the conference call. ETO is a gas used primarily as a sterilant for medical equipment and as a fumigant for spices. (Susan Bartow, 703-603-0065)

Acibenzolar First Team Meeting for Registration Review. On Tuesday, June 4, the acibenzolar team met to initiate the registration review of this chemical. Acibenzolar induces plant host resistance, and has no direct effect on the target species. Acibenzolar is registered to control or suppress plant diseases such as downy mildew on leafy vegetables, blue mold on tobacco, and black root, Fusarium wilt, and early season plant-parasitic nematodes on cotton. The acibenzolar docket is scheduled to open in December 2013. (Dana Friedman, 703-347-8827)

Status of Issuing GDCIs. PRD issued a Generic Data Call-In (GDCI) for 8 cases: triflusulfuron-methyl, thiacloprid, tefluthrin, rimsulfuron, norflurazon, pendimethalin, acetamiprid, and metribuzin during the period of May 30 to June 5. During FY2013, PRD has issued a total of 75 GDCI packages: 72 individual case GDCIs and 3 supplemental-GDCIs (to accommodate added studies for individual cases) for registration review. (Joseph Nevola, 703-308-8037; Meredith Scott, 703-308-0049; Shirley Miller, 703-308-0138)

# **ANTIMICROBIALS DIVISION**

EPA Evaluates Industry Model to Estimate Dietary Exposure to Sanitizers. EPA completed its evaluation of the Incidental Dietary Residential Exposure Assessment Model (IDREAM) developed by Exponent® at the request of the American Chemistry Council Biocides Panel (ACC). The model makes use of survey data of residential sanitizer use and food preparation habits on countertop surfaces. It also makes use of dietary consumption data derived from USDA's Continuing Survey of Food Intakes by Individuals 1994-98 (CSFII). Both ORD and OPP's Health Effects Division provided valuable input to the Antimicrobials Division's evaluation. EPA found that IDREAM is basically sound for its intended purpose but that several clarifications and additional documentation are necessary before the model can be used for dietary risk assessment. (William Hazel, 703-305-7677)

#### FIELD & EXTERNAL AFFAIRS DIVISION

<u>Pollinator Webinar with Regions and OECA</u>. Participants from eight EPA regions and the Offices of Compliance and Civil Enforcement attended a webinar on June 5. In these webinars, the Office of Pesticide Programs is both providing up-to-date information about pollinator protection and asking for information from the field. Topics covered included the pollinator risk assessment framework, best management practices, bee health, Region 7's coordination with lowa, bee incident reporting and two recent external stakeholder meetings. In addition, OPP received a tip about pesticide misters (pyrethrins) in the Southwest United States that may affect pollinators. (Yvette Hopkins, 308-1090; Tracy Lantz, 308-6415)

## BIOLOGICAL & ECONOMIC ANALYSIS DIVISION

BEAD Enters Laboratory Support Agreement with OECA. Over the past several months BEAD and OECA held several collaborative meetings to discuss how the OPP laboratories might assist with enforcement work. BEAD has supported OECA, Regions, and States with laboratory support and technical reviews for enforcement work in the past. Currently, OECA has a need to more fully support inspection activities by providing readily available laboratory support. These activities may include conducting additional inspections or collecting unplanned samples during a scheduled inspection. Laboratories supporting this work must have demonstrated their competence in performing the analyses and produce data that are legally defensible. The OPP laboratories are well versed in analysis of pesticide residues and formulation analysis, and analytical method development. The work supported by the support agreement will be conducted primarily by the Analytical Chemistry and Environmental Chemistry Branches. The agreement between OECA and BEAD is fully aligned with the Agency's ongoing efforts to more effectively leverage the expertise and resources of the Agency's laboratories. OECA has funded this effort through the end of this fiscal year and it is expected that the current agreement will be expanded to more fully meet OECA's laboratory support needs. (Diann Sims, 308-8129 and Mark Hartman, 308-0734)

<u>Laboratories Provide Comments on FIFRA Inspection Manual – Sampling Chapter.</u>

The Analytical Chemistry and Microbiology Laboratory Branches provided comments to Anne Pontius, Office of Regulatory Enforcement and Compliance Assurance, on the FIFRA Inspection Manual – Sampling Chapter. The chapter provides guidance to be followed by inspectors when conducting producer, marketplace or dealer inspections and obtaining samples for analysis or records from the inspection site. The laboratories provided advice on the volume of samples necessary for analysis including replicate testing and quality control requirements. In addition, it was recommended that Material Data Safety Sheets

(if available) accompany any sample sent to a lab for testing. The MSDS records are kept on site as part of a laboratory's chemical inventory plan and are used by the analysts to determine if any special precautions need to be taken with respect to sample handling. (Thuy Nguyen, 410-305-2905 and Susan Lawrence, 410-305-2954)

Review of Questionnaire for OECD Test Method Underway. In an effort to identify and mitigate sources of method variability, the Microbiology Laboratory Branch (MLB) is working with the stakeholder laboratories who participated in the 2012 eleven-lab collaborative study involving the quantitative OECD test method for measuring the efficacy of disinfectants. MLB led the collaborative study. A questionnaire, developed by an industry-led Efficacy Working Group (EWG) and MLB, was submitted to each participating lab to aid in identifying differences in technique, media preparation, and quality control practices associated with performing the OECD method. The results have been compiled by the EWG. MLB met with representatives of the EWG to discuss next steps and the best approach to summarize the findings. A meeting with all collaborating laboratories is scheduled for June 11th to review the findings of the questionnaire and to discuss the areas of further data collection. (Stephen Tomasino, 410-305-2976 and Susan Lawrence, 410-305-2954)

Multiple Biofilm Efficacy Experiments Completed. Over the past several weeks, the Microbiology Laboratory Branch (MLB) has conducted 4 biofilm efficacy tests using the CDC biofilm reactor with Pseudomonas aeruginosa and the Single Tube Method (ASTM E2871-12). The first two efficacy tests focused on evaluating commercially available hospital disinfectants with high levels of efficacy; three ready-to-use products and one concentrated product were tested. These 4 products yielded high log reductions (> 4.5 logs). In the second two efficacy tests, the analysts evaluated the three test chemicals used in the ASTM Inter-laboratory Study (ILS), each with a presumed high and a low efficacy treatment. While MLB did not participate in the ILS, the log reductions (LRs) generated by MLB are comparable with the mean LRs from the collaborative study. An anticipated next step for the biofilm project will be generating a Staphylococcus aureus biofilm. (Rebecca Pines, 410-305-2635 and Lisa Smith, 410-305-2859)

<u>Second Manuscript on the Use-dilution Method (UDM) Drafted.</u> The EPA accepts the UDM to support the registration of liquid antimicrobial products bearing claims to control microorganisms that pose a threat to human health on inanimate surfaces. Two technical papers are being used to support revisions to the performance standards for the AOAC UDM. This week, the revised manuscript entitled "A Statistical Model for Assessing Performance Standards for Quantitative and Semi-quantitative Disinfectant Test Methods" was re-submitted to the Journal of AOAC International (JAOAC). The paper was previously accepted by JAOAC (with revisions). A second paper, using the model detailed in the first paper,

entitled "Use of Statistical Modeling to Reassess the Performance Standard for the AOAC Use-dilution Method" was drafted and sent to statisticians at Montana State University (co-authors under contract with EPA) for review. The comments were received and the paper is now under internal review.

The second paper will be submitted to the journal for technical review following JAOAC's full approval of the first paper. (Stephen Tomasino, 410-305-2976)

# INFORMATION TECHNOLOGY & RESOURCES MANAGEMENT DIVISION

# New Web Page on Alternate Testing Approach for Assessment of Eye Irritation.

The ITRMD Web Team worked with FEAD to publish a new document titled "Use of An Alternate Testing Framework for Classification of Eye Irritation Potential of EPA Pesticide Products. This new document replaces the 2009 document and can be found at <a href="http://www.epa.gov/pesticides/science/eye-irritation.html">http://www.epa.gov/pesticides/science/eye-irritation.html</a> (Christine Tran, 703-305-1577)

OPP FOIA Request Status Report - May 27 -31, 2013								
Requests Received		Requests Closed			Requests Open			
FY13	This Week	FY13	FYTD	This Week	FY13	Prior Years	Total	
326	6	188	277	4	138	131	269	

(Ana Espinoza, 703-347-0102)

NRDC submitted a FOIA request concerning conditionally products with the following active ingredients: Acetamiprid, imidacloprid, dinotefuran, thiacloprid, and thiomethoxam. NRDC wants all the records submitted and any agency DER/review in regards to the products becoming non-conditional registrations. (E. Ingram 305-5456)

### BIOPESTICIDES & POLLUTION PREVENTION DIVISION

New Microbial Al Approved. On May 31, BPPD's Microbial Pesticides Branch (MPB) registered a manufacturing-use pesticide product and an end-use pesticide product containing the new active ingredient, *Bacillus pumilus* strain BU F-33. The end-use pesticide product, Integral F-33®, will be commercially applied to seed (e.g., carrot and tomato) to elicit induced systemic resistance in plants, thereby enhancing their defense against certain pathogens. In conjunction with these registrations actions, BPPD's MPB established an exemption from the requirement of a tolerance for residues of this bacterium under 40 CFR 180.1322. (Jeannine Kausch, 347-8920)

<u>BPPD Director Presents at Regulatory Conference</u> On June 4, Keith Matthews presented at BASF's North American Annual Regulatory Conference in Research Triangle Park, North Carolina. Keith provided an overview of regulation and registration for biochemicals, microbials, and plant-incorporated protectants. He also provided an overview of PRIA 3, and trends in biopesticides and biotechnology. The informative presentation was well received. (Nicole Berckes, 308-0152)

#### **FNVIRONMENTAL FATE & FFFFCTS DIVISION**

Wildlife Endocrinology Seminar. On June 6, EFED hosted a Wildlife Endocrinology seminar, featuring Dr. Richard Judson from the National Center for Computation Toxicology, ORD/EPA. Dr. Judson presented his work on using multiple *in vitro* high-throughput screening assays for the Estrogen Receptor (ER) pathway to distinguish true ER activity from false positive activity due to assay interference. During the seminar, Dr. Judson demonstrated the results of using this method across a library of 1777 chemicals that included ER reference chemicals, other environmental estrogens as well as other chemicals expected to cause assay interference such as solvents, detergents, and reactive compounds. He also described how the results from this analysis can yield a prioritized list of chemicals to consider for further testing as potential endocrine disruptors. (Michael Wagman, 703-347-0198; Catherine Aubee, 703-347-8029; Elyssa Gelmann, 703-347-0236.)

**OPP Meets with Penn State Researchers**. On June 3, representatives from EFED, PRD, and RD met with researchers at Pennsylvania State University to discuss their recent studies examining the potential effects of pesticide mixtures on bees and to learn about their efforts to develop a honey bee population model. The researchers have been developing field tesing methods, using both honey bees and native bees such as the blue orchard bee, to examine effects of complex mixtures of pesticides typically found in Pennsylvania apple orchards on individual bee development. The data collected on individual bees have in turn been used as input to Penn State's bee population model for extrapolation to potential colony-level effects. The meeting also provided an opportunity for the researchers to learn about current EPA efforts to assess and manage risks associated with pesticides. The researchers believe that multiple factors may be involved in honey bee declines such as varroa mites, pathogens, nutrition, and pesticides. With respect to pesticides, the group discussed the need to place greater emphasis on educating pesticide users (growers and beekeepers in both the agricultural and residential settings) on the risks associated with pesticides and the need for integrated pest management practices to reduce the reliance on chemicals. (Tom Steeger, 703-305-5444; Meredith Laws, 703-308-7038).

#### HEALTH EFFECTS DIVISION

Meeting With USDA On Plant Protection and Quarantine (PPQ) Uses of Methyl Bromide: Senior level OPP management and several staff members participated in a meeting (5/31/13) with USDA PPQ senior level management focused on the PPQ uses for methyl bromide. Specifically, the major concerns were associated with the continuation of the existing Section 18s for various commodities and the quarantine use for potato cyst nematode (PCN) in Idaho. The topics which were discussed included a statement of objectives and goals, a description of the Section 18 status, the status of the current risk management efforts for commodity uses, how models are used for risk assessment, and a path forward for collaboration. Some actions items were defined that include determining the size of fields treated for PCN, the size of structures treated for Section 18 uses especially those which need specific approval (i.e., over 25,000 ft³), and defining how an all commodity approach could be considered. (Jeff Dawson, 305-7329)

ORD provides CEB staff an overview of SHEDS-lite: ORD Staff (Haluk Ozkaynak and Kristin Isaacs) provided CEB staff with an overview of SHEDS-Lite. This version was developed as part of ORD's Chemical Safety for Sustainability (CSS) program's workplan to develop exposure related information that can be used for various purposes, including prioritizing chemicals for different program offices. Most of the work to date is focused on OCSPP (OPPT and OPP) chemicals. SHEDS-lite currently focuses on residential (non-dietary) sources of exposure to the general population, providing a cross section of single day exposure estimates (SHEDS Multimedia provides within day estimates over a 365 day duration; dietary sources are being incorporated into the model. ORD staff plan to have a draft journal article available for interagency review later this summer. (Steve Nako, 308-8092; Matt Crowley, 305-7606)

#### **REGISTRATION DIVISION**

Import Tolerances Established for Triforine On May 29, 2013, the Federal Register, [78 FR 32146] published a final rule establishing import tolerances (without U.S. registrations) for residues of triforine, including its metabolites and degradates, in or on tomato at 0.5 ppm; and blueberry at 1.0 ppm. Triforine is a systemic amide fungicide with protectant, eradicant, and curative characteristics. All U.S. food uses of triforine were voluntarily cancelled in 1996, and the associated tolerances were revoked in a final rule published on July 23, 2004 [69 FR 43918]. Outside the U.S., triforine continues to be used on food crops, turf, and ornamentals. Summit Agro North America Holding Corporation petitioned the Agency to approve these import tolerances. (Heather Garvie, 703/308-0034)

Tolerances Published in the Federal Register for Propamocarb On June 5, 2013, the Federal Register published a final rule which established a tolerance for residues of propamocarb in or on succulent lima bean. Propamocarb is a carbamate fungicide that interferes with fungal synthesis of phospholipids and fatty acids. The flowable-concentrate (FIC) formulation [EPA Registration 264-678] associated with this use is currently registered for the control of fungal diseases on lettuce, potatoes, fruiting vegetables, and cucurbit vegetables. The use on lima beans was registered on May 29th after the final rule was posted with the Delaware Department of Agriculture. Interregional Research Project Number 4 (IR-4) petitioned the Agency for this use, and Bayer CropScience owns the pesticide product labeling associated with this action. (Laura Nollen, 703/305-7390)

New Tolerances Established for Imidacloprid On June 5, 2013, the Federal Register [78 FR 33736] published a final rule establishing permanent tolerances for residues of imidacloprid in or on fish and fish-shellfish, mollusc requested by the Interregional Research Project Number 4 (IR-4) under the Federal Food, Drug, and Cosmetic Act (FFDCA). The Willapa-Grays Harbor Oyster Growers Association owns the registration for these uses under two product labels, Protector 0.5G and Protector 2F. Imidacloprid provides an effective and "safer" alternative pesticide for this market over carbaryl products. In addition, this regulation establishes timelimited tolerances for residues of imidacloprid in or on sugarcane, cane and sugarcane, molasses associated with the use of the pesticide on sugarcane under Section 18 emergency exemptions granted to the state of Louisiana. The time-limited tolerances expire on December 31, 2015. Imidacloprid is an insecticide registered for use on a variety of food crops to control aphids, cucumber beetles, and whiteflies as well as use in products for ornamental turf/plants, seed treatments and pet care. A member of the pyridylmethyl-amine chemical class of compounds, imidacloprid's pesticidal activity mimics the action of acetylcholine at the nerve synapse and impairs normal nerve function causing tremors, loss of coordination and eventual death of the insect. (Sidney Jackson, 703/305-7610)

Registration Actions Completed Under the Pesticide Registration Improvement Act (PRIA)								
Chemical	Company	Registration	Action	Due Date	Response			
		Number	Code*		Date			
The Fungicide Branch granted:								
Captan	United Phosphorus, Inc.	70506-297	R310	5/31/2013	5/31/2013			
	Dominic Schuler, 703/347-0260							
The Insecticide Branch granted:								
Imiprothrin	McLaughlin Gormley King	1021-2599	R310	6/21/2013	6/4/2013			
	Company							
Linda DeLuise, 703/305-5428								
Esfenvalerate	S. C. Johnson & Son, Inc.	4822-598	R300	6/4/2013	6/4/2013			
Carmen Rodia, 703/306-0327								

R300 – New product; identical or substantially similar in composition and use to a registered product; no data review or only product chemistry data; cite-all data citation or selective data citation where applicant owns all required data or submits specific authorization letter from data owner; category also includes 100% repackage of registered end-use or manufacturing-use product that requires no data submission or data matrix and R310 – New end-use or manufacturing use product; requires review of data package within RD; includes reviews and/or waivers of data for only: product chemistry and/or acute toxicity and/or public health pest efficacy.

	Registration Actions Granted Under FIFRA Section 18 Emergency Exemptions							
State/Federal Agency	Chemical Emergency Exemption Number	Product Name EPA Reg/ File Symbol	Crop/Site	Pest	Authorization Date			
Specific Exemption(s):								
Louisiana	Imidacloprid 13-LA-06	Admire® PRO Systemic Protectant (264-827)	Sugarcane	West Indian Canefly	5/23/2013			
	Debra Rate, 703/306-0309							
Delaware	Dinotefuran 13DE04-05	Venom (59639- 135), Scorpion 35SL (10163-317)	Pome Fruit Stone Fruit	Brown Marmorated Stinkbug	5/31/2013			
Maryland	Dinotefuran 13MD06-07	Venom (59639- 135), Scorpion 35SL (10163-317)	Pome Fruit Stone Fruit	Brown Marmorated Stinkbug	5/31/2013			
Michigan	Dinotefuran 13Ml03-04	Venom (59639- 135), Scorpion 35SL (10163-317)	Pome Fruit Stone Fruit	Brown Marmorated Stinkbug	5/31/2013			
North Carolina	Dinotefuran 13NC04-05	Venom (59639- 135), Scorpion 35SL (10163-317)	Pome Fruit Stone Fruit	Brown Marmorated Stinkbug	5/31/2013			
Pennsylvania	Dinotefuran 13PA06-07	Venom (59639- 135), Scorpion 35SL (10163-317)	Pome Fruit Stone Fruit	Brown Marmorated Stinkbug	5/31/2013			
Virginia	Dinotefuran 13VA04-05	Venom (59639- 135), Scorpion 35SL (10163-317)	Pome Fruit Stone Fruit	Brown Marmorated Stinkbug	5/31/203			
West Virginia	Dinotefuran 13WV06-07	Venom (59639- 135), Scorpion 35SL (10163-317)	Pome Fruit Stone Fruit	Brown Marmorated Stinkbug	5/31/2013			
Andrea Conrath, 703/308-9356								

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